OCT 1 1 2000

510(k) SUMMARY

K002983

Submitter's Name: Warepalmy Enterprise LLC (USA)
1725 NE Orenco Station Parkway
Hillsboro, OR 97124
(503) 693-6516

Date summary prepared: September 18, 2000

Device name:

Proprietary name:	C.T.M. Power Chair HS-5600
Common or usual name:	Power chair.
Classification name:	Powered wheelchair, Class II, 21 CFR 890.3860.

Legally marketed device for substantial equivalence comparison:

Rascal/Viva™ Powerchair submitted by Electric Mobility Corp. and cleared for marketing under 510(k) #K924515.

Description of the device:

The C.T.M. Power Chair HS-5600 is an indoor/outdoor powered wheelchair that is battery operated. It has a base with four wheels, an adjustable padded seat with armrests and headrest, and a controller attached to one armrest which allows the rider to control the movement of the chair. It can be disassembled for transport and is provided with a battery charger.

Intended use of device:

The device is an indoor/outdoor powered wheelchair that provides transportation for a disabled or elderly person.

Technological characteristics:

The device features and use parameters of the C.T.M. Power Chair HS-5600 and Rascal/Viva are very similar. Both are battery operated, have two motors, and have automatic braking systems. Batteries and charging recommendations are identical. Battery chargers are provided with both wheelchairs, but the Rascal/Viva charger is built-in. Use parameters are very similar, varying only in minor parameters such as maximum travel range of the respective wheelchairs.

Testing conducted:

Tests listed in the *Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three Wheeled Vehicles,* July 1995, were conducted and the results included in the subject 510(k) submission.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2000

Warepalmy Enterprise LLC (USA)
c/o Mr. Robert S. McQuate
R.S. McQuate & Associates, Inc.
3636 East Columbine Drive
Phoenix, Arizona 85032-7372

Re: K002983
Trade Name: C.T.M. Power Chair, Model HS-5600
Regulatory Class: II
Product Code: ITI
Dated: September 21, 2000
Received: September 25, 2000

Dear Mr. McQuate:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K002983

Device name: C.T.M. Power Chair HS-5600

Indications for Use:

The C.T.M. Power Chair HS-5600 is an indoor/outdoor powered wheelchair that provides transportation for a disabled or elderly person.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

NPO for (mlw)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002983

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)